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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/745,095	12/20/2000	Leah E. Appel	PC10818AJTJ	8852

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EXAMINER
GOLLAMUDI, SHARMILA S

ART UNIT	PAPER NUMBER
1616	

DATE MAILED: 03/19/2003

14

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/745,095	Applicant(s) APPEL ET AL.	
	Examiner Sharmila S. Gollamudi	Art Unit 1616	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *06 January 2003* .

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *2, 7-9, 12-32, 44-45, 49-51, 56-57, 63-81, 88-97, 101, 103-108, 118-122, 124, and 130-31* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *2, 7-9, 12-32, 44-45, 49-51, 56-57, 63-81, 88-97, 101, 103-108, 118-122, 124, and 130-31* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

DETAILED ACTION

Status of Application

Receipt of Extension of Time, Rule 132 Declaration, Supplementary IDS, and Amendment B received on January 6, 2003 are acknowledged. Claims 2, 7-9, 12-32, 44-45, 49-51, 56-57, 63-81, 88-97, 101, 103-108, 118-122, 124, and 130-31 are included in the prosecution of this application. Claims 1, 3-6, 10-11, 33-43, 46-48, 52-55, 58-62, 82-87, 98-100, 109-117, 123, and 125-129 are cancelled. Claims 58-62 will be rejoined if the claims are found to be allowable.

Response to Amendment

The Declaration under 37 CFR 1.132 filed January 6, 2003 is sufficient to overcome the rejection of claims 2, 7-9, 12-15, 17,18, 22, 25-26, 44-45, 49-51, 56, 64-74, 79-81, 88-96, 101, 103-108, 118-122, and 124. Applicant has shown that the 102(b) reference does not have instant swelling ratio.

Response to Arguments

Applicant's arguments have been considered but are moot in view of the new ground(s) of rejection based on the IDS submitted.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 2, 7-9, 12-32, 44-45, 49-51, 56, 63-81, 88-97,101, 103-108, 118-122, 124, and 130-131 rejected under 35 U.S.C. 103(a) as being unpatentable over Wong et al (4,765,989) in view of Stevens et al (5,897,874).

Wong et al teach an osmotic device for administering drugs. The device contains a first composition containing nifedipine, polyethyleneoxide (PEO), hydroxypropylmethylcellulose (HPMC), and magnesium stearate. The second composition contains PEO, HPMC, sodium chloride, and magnesium stearate. A semipermeable wall made of 95% cellulose acetate having an acetyl content of 39.8% and 5% PEG surrounds the two compositions. The device has at least one passageway. (Examples). The osmopolymers used in the invention have an expansion factor of 2-50 fold volume increase (col. 16, lines 3-5). The mass ratio of the first composition to the second composition is taught on column 16. The swelling ratio is taught on columns 17 and 18. Wong teaches the active agent may in various forms and dispersed in suspending agents such as PVP (col. 18, line 43 to col.19, line 5). Agents such as tartaric acid, mannitol, sucrose, and sodium chloride are taught. Solvents for

the semipermeable membrane are taught on column 20, lines 11-35. Release of the drug is taught in Figure 9.

Wong et al does not teach all instant parameters or sodium glycolate.

Stevens et al teach a delivery device with a drug and expandable excipient. The expandable excipient is a water-swellable material that has the overall swelling capacity of 200-400% (col. 4, lines 44-48). The swellable materials may be chosen from PEO polymers, sodium starch glycolate, microcrystalline cellulose, etc. (col.3-4). Stevens teaches the conventional hardness of a tablet is 4kg (col. 5, lines 5-70. The drug may be mixed with a carrier material and is positioned over the hydrogel layer (col. 6, lines 26-27). The swelling factor is taught on column 7.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to combine the teachings of Wong et al and Stevens et al since both teach delivery devices containing expandable excipients. One would be motivated to look to Stevens et al since the reference teaches the instant tablet hardness is conventional in the art. Further, Stevens teaches the suitability of sodium starch glycolate or PEO as an expandable excipient with a swelling capacity of over 200%. Lastly, both references provide the general guidance in manipulating factors such as water flux, swelling capacity, release rate, interchangeable excipients, etc. Therefore, one would be motivated to manipulate such factors to yield the desired parameters.

Claim 57 is rejected under 35 U.S.C. 103(a) as being unpatentable over Wong et al (4,765,989) in view of Stevens et al (5,897,874) in further view of From

hypertension to angina to Viagra (Jim Kling, Modern Drug Discov ry, 1998, 1(2), 31, 33-34, 36, 38.)

As set forth above, Wong and Stevens teach delivery device containing expandable excipients. Wong teaches the suitability of several drugs such as antihypertensives.

Wong and Stevens do not teach instant drug

Kling teaches Viagra as a drug for hypertension or erectile dysfunction.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to use sildenafil citrate in the device of Wong or Stevens. One would be motivated to do so if one wanted to treat erectile dysfunction. Further, one would be motivated to do so with the expectation of similar results since Wong teaches the use of antihypertensives in the device.

Conclusion

Applicant's submission of an information disclosure statement under 37 CFR 1.97(c) with the fee set forth in 37 CFR 1.17(p) on January 6, 2003 prompted the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 609(B)(2)(i). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the

shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sharmila S. Gollamudi whose telephone number is (703) 305-2147. The examiner can normally be reached on M-F (7:30-4:30).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jose Dees can be reached on (703) 308-4628. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 305-3014 for regular communications and (703) 305-3014 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

SSG

March 12, 2003

MICHAEL G. HARTLEY
PRIMARY EXAMINER